REMARKS

Claims 1, 3, 5-11, 13-15, 36-51, and 60-61 are pending. Claims 3, 5-11, 45-48, and 50-51 are withdrawn as they are directed to a non-elected species. Claim 16 is canceled herein. The amendment to claim 1 is supported by original claim 16 and paragraph [0014] (human subject). The amendment to claim 14 is supported in the specification, for example, at paragraph [0019]. The amendment to claim 15 is to correct a typographical error. The amendments to claims 36, 38-42, and 60-61 are supported, for example, in the specification at paragraph [0014]. The amendment to claim 61 is supported in the specification at paragraph [0072].

Examiner Interview

On December 9, 2008, Examiner Neil Levy had a personal interview with Dr. Gerrit Klaerner (inventor), Ronald Krasnow (representing Relypsa Inc.) and Janet S. Hendrickson and Kathleen M. Petrillo (attorneys for Applicants). In the interview, the parties discussed the final rejection mailed on November 12, 2008. Examiner Levy stated that if claim 1 were limited to humans and the polymers of claim 16 were incorporated into claim 1, the outstanding rejections would be overcome.

35 U.S.C. § 112

Reconsideration is requested of the rejection of claim 1, 13-15, 36-44, 60, and 61 as not satisfying the enablement requirement of 35 U.S.C. § 112, first paragraph. While Applicant believes the arguments presented in the response filed on August 20, 2008 are persuasive, to expedite prosecution, claim 1 has been amended in a manner that the Office's prior Office action and interview summary indicated would overcome this rejection. Thus, claims 1, 13-15, 36-44, 60, and 61 satisfy the enablement requirement of 35 U.S.C. § 112.

35 U.S.C. § 103 Rejection

Reconsideration is requested of the rejection of claims 1, 13-15, 36-44, 60, and 61 as unpatentable under 35 U.S.C. § 103(a) over EP 0349453 (Martani) in view of U.S. Patent No. 5,846,990 (Murugesan) and Notenbomer (EP 0730494). Again, while Applicant believes the arguments presented in the response filed on August 20, 2008 are persuasive, to expedite

prosecution, claim 1 has been amended so that is it directed to humans and incorporates the polymers of claim 16; the interview summary indicated these amendments would overcome this rejection. Thus, claims 1, 13-15, 36-44, 60, and 61 as patentable over EP 0349453 (Martani) in view of U.S. Patent No. 5,846,990 (Murugesan) and Notenbomer (EP 0730494) under 35 U.S.C. § 103(a).

Provisional Double Patenting Rejection

The analysis employed in an obvious-type double patenting rejection parallels the guidelines of a 35 U.S.C. § 103 obviousness determination.[1] However, an important distinction exists. A rejection for obviousness must be based on a comparison of the claimed invention to the entirety of the disclosure in the prior art reference, whereas an obviousness-type double patenting rejection must be grounded on a comparison of the claimed invention to the claims, **and only the claims**, of the reference.[2]

It is respectfully submitted that in light of the amendments made herein and the discussion of non-obviousness during the interview, the subject matter of the claims of the present application would not have been obvious in view of the claims of U.S. Patent No. 7,488,495 (U.S. Patent Application No. 10/965,274) or U.S. Patent Application No. 11/096,209. When evaluating the scope of a claim, every element of the claim must be considered.[3]

A. U.S. Patent Application No. 10/965,274

Reconsideration of the rejection of claims 1 and 36-44 as being unpatentable for nonstatutory obviousness-type double patenting over claims 1, 5, 8-17, and 30 of U.S. Patent Application No. 10/965,274 is respectfully requested. The '274 application is now US Patent 7,488,495, and claims 1, 5, 8-17, and 30 of the '274 were canceled. Nonetheless, it is respectfully submitted that the subject claims 1 and 36-40 are patentable in view of the '495 patent. The current claims are generally directed to methods for removing sodium from a patient suffering from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis,

[1] In re Braat, 937 F.2d 589 (Fed. Cir. 1991).
[2] Purdue Pharma L.P. v. Boehringer Ingelheim GMbH, 98 F.Supp.2d 362, 392, 55 USPQ2d 1168, 1190 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359, 57 USPQ2d 1647 (Fed. Cir. 2001).
[3] See, e.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

chronic renal insufficiency, fluid overload, or sodium overload by administration of various cation exchange polymers having an *in vivo* sodium binding capacity of 4 mmol or more per gram. The '495 patent claims are directed to methods of treating hyperkalemia by administering particular cation-exchange polymers having a combination of counterions. Because the claims of the '495 patent do not include the element of removing sodium from a subject suffering from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload, the claims do not include all the elements of instant claims 1 and 36-44. Moreover, upon contemplation of the claims of the '495 patent, a person skilled in the art would not have found it obvious that the human subject of claim 1 herein suffered from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload. Thus, claims 1 and 36-44 are patentable over the claims of the '495 patent.

B. U.S. Patent Application No. 11/096,209

Reconsideration of the rejection of claims 1, 13-14, 36-43, 60, and 61 as being unpatentable for nonstatutory obviousness-type double patenting over claims 43-49, 52-59, and 61-64 of U.S. Patent Application No. 11/096,209 is respectfully requested. Subject claim 1 is directed to a method for removing sodium from a patient suffering from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload by administration of various cation exchange polymers having an *in vivo* sodium binding capacity of 4 mmol or more per gram. Like the '495 patent, the claims[4] of the '209 application are generally directed to methods of removing potassium from the gastrointestinal tract of a mammal in need thereof by administering a specified crosslinked α-fluoroacrylic acid polymer, a crosslinked difluoromaleic acid polymer, or a salt thereof. None of the '209 claims include the element of removing sodium from a patient suffering from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload and so the '209 claims do not include all the elements of the subject claims. Moreover, upon contemplation of the claims of the '209 application, a person skilled in the art would not have found it obvious that the human subject of

[4] It appears that the reference to claims 43-49, 52-59, and 61-64 of U.S. Patent Application No. 11/096,209 is incorrect.

instant claim 1 suffered from hypertension, congestive heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload. Thus, claims 1, 13-14, 36-43, 60, and 61 are patentable over the claims of the '209 application.

Rejoinder

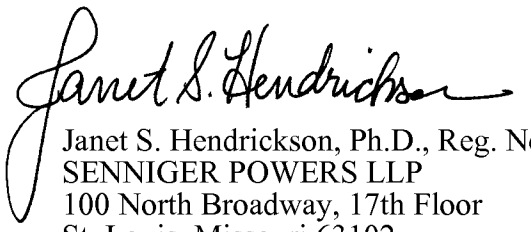
Pursuant to MPEP §821.04, Applicants again request rejoinder of withdrawn claims 3, 5-11, 45-48, and 50-51 as they depend from claim 1, require all of the limitations of claim 1, and claim 1 is amended to include specific acid resin polymers. Furthermore, applicants submit that these claims are allowable over the references relied upon by the Office.

CONCLUSION

Applicant submits that the present application is in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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